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10/021,667	10/29/2001	Soumya P. Sahoo	20768	7049

7590

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EXAMINER

SOLOLA, TAOFIQ A

ART UNIT

PAPER NUMBER

1626

DATE MAILED: 05/19/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/021,667

Applicant(s)

SAHOO ET AL.

Examiner

Taofiq A. Solola

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☐ Claim(s) 1-32 and 35-56 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-32 and 35-56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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Claims 1-32, 35-56 are pending in this application.

Claims 33-34 are canceled.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 29-30, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite because claim 29 is an independent claim but rely on claim 1 for the definition of the substituents of formula Ia. Claim 29 must stand alone to define the invention. Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6, 8, 10, 12, 14-16, 21-22, 24-24, 35-43, 44-45, 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Clemens et al., US 5,563,164.

Clemens et al., disclose compounds of general formula I, examples 6, 12, their compositions and several methods of use. See the abstract; column 1, line 65; and columns 36-39.

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Claims 1-4, 6, 8, 10, 12, 14-17, 21-22, 29-30, 35, 44-45, 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Penning et al., J. Med. Chem., (1995), Vol. 38, No. 6, paged 858-868.

Penning et al., disclose compounds 4-5, 7-9, 11, 13, 16, 15-19, 23-24, 27, 29, their composition and method of use as anti-inflammatory. See also compounds in tables 1 and 2

Claims 1-6, 8, 10, 12, 14-16, 21-22, 24-25, 29-30, 35, 44-45, 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Djuric et al., US 5,073,562; and Sofia, US 5,352,690, individually.

Djuric et al., disclose compounds having generic formulae I, II, examples 5, 7-14, 16-17, 21, 23-29, 32-33; their compositions and method of use as anti-inflammatory.

Sofia discloses compounds having generic formula I, compounds in scheme 3, columns 9-10, scheme 4, columns 11-12, examples 9-10, their compositions (columns 55-58) and method of use as anti-inflammatory. See claims 1-23.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6-7, 9, 11, 13, 26-28, 31-32, 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clemens et al., US 5,563,164; Penning et al., J. Med. Chem., (1995), Vol. 38, No. 6, paged 858-868; Djuric et al., US 5,073,562; and Sofia, US 5,352,690, individually.

Applicant claims compounds having generic formula I, wherein R1 is alkyl, R2-R3, R5-R9 are each H, R4 is alkoxy, optionally substituted cycloalkyl or heterocyclic (hetcyc), n is 3-4, X

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and Y are each oxygen. Applicant position isomer of the compounds wherein X is attached to the benzopyran at position 6 (claim 9) and stereoisomers in claims 31-32. Applicant also claim a method of use for treating cachexia (general physical wasting condition due to chronic disease).

Determination of the scope and content of the prior art (MPEP §2141.01)

Clemens et al., teach compounds of general formula I, examples 6, 12. See the abstract; column 1, line 65; and columns 36-39, and several methods of use. The compounds are represented by racemic structure; n is 2; R1-R3, R5-R9 are each H; R4 is substitute phenyl or alkoxy; n is 2; X and Y are each oxygen.

Penning et al., teach compounds 4-5, 7-9, 11, 13, 16, 15-19, 23-24, 27, 29, and method of use as anti-inflammatory. See also compounds in tables 1 and 2. The compounds are represented by racemic structure wherein R1-R3, R5-R9 are each H, R4 is specific heterocyclics; n is 2; X and Y are each oxygen.

Djuric et al., teach compounds having generic formulae I, II, examples 5, 7-14, 16-17, 21, 23-29, 32-33, and method of use as anti-inflammatory. The compounds are represented by racemic structure wherein R1-R3, R5-R9 are each H, R4 is specific heterocyclics; n is 2; X and Y are each oxygen.

Sofia discloses compounds having generic formula I, compounds in scheme 3, columns 9-10, scheme 4, columns 11-12, examples 9-10, and method of use as anti-inflammatory. See claims 1-23. The compounds are represented by racemic structure wherein R1-R3, R5-R9 are each H, R4 is alkoxy; n is 2; X and Y are each oxygen.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

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The difference between the instant invention and that of Clemens et al., Penning et al., Djuric et al., and Sofia is that applicant is claiming R1 is alkyl; n is 3-4 and isomers instead of n is 2, and racemate by Clemens et al., Penning et al., Djuric et al., and Sofia.

**Finding of prima facie obviousness---rational and motivation (MPEP §2142.2413)**

However, a novel and useful compound, which is isomeric with a compound of prior art, is not patentable where the new compound is not shown to possess new and unexpected utilities. *In re Norris*, 84 USPQ 458. Applicant is reminded that when the difference between compounds is only in the length of a carbon chain such compounds are adjacent homologs. However, adjacent homologs are prima facie obvious. *In re Henze*, 85 USPQ 261 (1950). Also, a chronic disease, such as, would necessarily results in caxechia.

Therefore, the instant invention is prima facie obvious from the teaching(s) of Clemens et al., Penning et al., Djuric et al., and Sofia. One of ordinary skill in the art would have known to claim the isomers and adjacent homologs of the compounds of Clemens et al., Penning et al., Djuric et al., and Sofia at the time the instant invention was made. The motivation is that it is well known in the art that isomers have similar biological and chemical activities. This also true of adjacent homologs.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-32, 35-56 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-46 of copending Application No. 09/961,841. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Applicant's arguments filed 3/31/03 have been fully considered but they are not persuasive. Applicant contends that the subject matter in this application and 09/961,841, are not the same or overlapped. This is not persuasive because applicant provides no evidence or argument in support this assertion.

#### **Warning**

Applicant is advised that should claim 36-43 are found allowable, the claims will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

#### ***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Taofiq A. Solola whose telephone number is (703) 308-4690.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph McKane, can be reached on (703) 308-4532. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.



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TAOFIQ SOLOLA  
Art Unit 1626  
PRIMARY EXAMINER

May 18, 2003